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EXAMINER	
KIM, JENNIFER M	
ART UNIT	**PAPER NUMBER**
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/706,765	LIPSKY, RICHARD	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *11,12 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 13-26, 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/15/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Naloxone as a species of opioids antagonist is acknowledged. The traversal is on the ground(s) that no additional burden is placed on the examiner to search both species because the species are sufficiently closely related that a search and examination of one will necessarily cover a search and examination of other, and that they are both opioids antagonists. This is not found persuasive because the claims are drawn to compounds having unrelated structural features. Therefore, undue burden would place on the examiner to search each of the active compounds to be utilized having its own unique chemical/physical characteristics. The required searches are not coextensive particularly, non-patent literature would place serious burden on the Examiner. Therefore, the requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 1-10 and 13-28 have been examined only to the extent of Applicant's elected species. Claims 11 and 12 are withdrawn from consideration because they are non-elected invention.

Specification

The use of the **various** trademarks (e.g. PERCODAN, page 5) has been noted in this application. It should be capitalized wherever it appears and be accompanied by

the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

There is a typographical error on page 4 [0014], "Naxloxone" should be "naloxone".

Claim Objection

Claims 18, 23 and 25 are objected to because of the following informalities: There is a typographical error in the claims. The term "Trazedone" should be "Trazodone". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written description

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had **possession** of the claimed invention.

Claims 1-5 are drawn to a method for opiate detoxification comprising administering **an opioids antagonist** at a rate greater than 0.4mg/kg/hr. The claims thus encompass a broad genus of **an opioids antagonist**.

The instant specification does not describe or exemplify all **opioids antagonists**, much less a structural moiety to identify any compounds qualified as **an opioids antagonist**. Accordingly, the instant specification does not provide a basis for one of skill in the art to envision the structural/physical characteristics of such compounds. The premise for the limitation of **an opioids antagonist** appears to be derived from the observation in the instant specification of specific compounds Naloxone and REVEX. The specification does not however, indicate why one should assume based on the disclosure of the employment of these two **opioids antagonists** that any species of the broad genus of **an opioids antagonist** is represented without identifying the chemical structural moiety related to the compounds. Given this lack of description of a sufficient number of the representative species encompasses by the genus of the claim, the specification fails to described the claimed invention in such full, clear, concise, and exact terms regarding the chemical structure-function relationship that a skilled artisan would not recognize that Applicants were in possession of the claimed invention, "**an opioids antagonist**".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 9, 13-16, 18, 22, 23 and 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4, 9, 13-16, 18, 22, 23 and 25-27 contain the trademark/trade name PRECEDEX, REVEX, VALIUM XANAX and TRAZODONE. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. It is suggested to delete the trade names and use their common chemical names (e.g. diazepam instead of VALIUM).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by McDonald et al. (April 2001).

McDonald et al. teach that opioids detoxification was produced by infusion of 25mg naloxone for 30 minutes. (It is noted that McDonald et al's rate of infusion in units per hour is equivalent to 50mg/hr; subject weighing 50kg based on the specification [0030]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over McDonald et al. (April 2001).

Mc Donald et al. as applied as before.

McDonald et al. do not teach the administration of 50mg naloxone in a single dosage.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer naloxone in divide dosages of 50mg in a single dosage for the treatment of opiate addiction or detoxification because McDonald et al. teach that the naloxone is effective for the opiate detoxification with employment of about 50mg daily dosage of naloxone (25mg of naloxone followed by 24 hour infusion of 1mg per hour). One would have been motivated to make such a modification in order to successfully treat opiate detoxification by single convenient bolus administration of naloxone. There is a reasonable expectation of successfully treating opiate detoxification with 50mg single dosage of naloxone because the effectiveness of 50mg daily dosage administration of naloxone in treatment of opioids detoxification is well taught by McDonald et al.

Claims 4, 9, 13, 14 and 17-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over McDonald et al. (April 2001) in view of Legarda Ibanez (U.S.Patent No. 6,103,734) and further in view of Takrouri et al. (2002) and Gooberman et al. (U.S.Patent No. 5,789,411).

McDonald et al. as before.

McDonald does not teach the administration of Precedex and the rate of administration and detoxification process comprising anesthetizing, intubating, stabilizing the patient, giving Valium, Xanax, Trazodone, antiemetics and antiperistaltic agents, administration of antihistamine agent prior to administering opioids antagonist and further administering Revex.

Legarda Ibanez teaches a method to suppress opiates dependence with combination of chemical compounds used as a medicament comprising administering antiemetic, sedating or anesthetizing agent, H2-antihistamine, benzodiazepine and alpha-adrenergic agent such as clonidine. (claims 1-13). Legarda Ibanez teaches that an alpha-adrenergic agonist such as clonidine increases sedation and diminishes the symptomatology of the syndrome of opiate abstinence. (column 2, lines 39-42). Legarda Ibanez teaches the combination of chemical compounds in opiate dependence treatment allows an ultra rapid approach for the detoxification of polydrug users who are addicted to heroin and/or Methadone or other opiates. (column 3, lines 12-15).

Takrouri et al. teach that dexmedetomidine (Precedex) is a potent new alpha-2 adrenoreceptor agonist more than 7 times of alpha –2 activity than clonidine. Takrouri et al. teach that dexmedetomidine has potent sedative, analgesic and sympatholytic effects blunt the cardiovascular responses without unexpected toxicity. (abstract).

Gooberman et al. teach that rapid opioids detoxification procedure with naloxone comprising sedating a patient with an anesthetic agent comprising administering a diarrhea suppressant agent, neuromuscular blocking agent. (abstract, claims). Gooberman et al. also teaches that nalmefene (Revex) can be administered to the patient after the initiation of the withdraw with naloxone. (column 5, lines 34-37).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the opioids detoxification method taught by McDonald and employ combination of chemical compounds such as antiemetic, sedating or anesthetizing agent, H2-antihistamine, benzodiazepine and alpha-adrenergic agent

taught by Legarda Ibanez because Legarda Ibanez teaches that the combination of chemical compound with naloxone detoxification allows an ultra rapid approach for the detoxification of polydrug users who are addicted to heroin and/or Methadone or other opiates. With regard to the employment of Precedex (dexmedetomidine) and nalmefene (Revex) as well as the specific benzodiazepine (e.g. Valium, Xanax) are all deemed obvious because the usefulness of the active agents in combination with naloxone in opioids detoxification has been collectively taught by the combined teachings of the references. It would have been obvious to one of ordinary skill in the art to further modify the method of Legarda Ibanez and replace clonidine with dexmedetomide as an alpha adrenergic agonist in view of Takrouri et al. who teach that dexmedetomidine is more potent than clonidine in treating sedation without toxicity. It would have been obvious to one of ordinary skill in the art to further incorporate Revex in opioids detoxification comprising naloxone as modified by Legarda Ibanez because the administration of nalmefene (Revex) to a patient after the initiation of the withdraw process with naloxone is well known in view of Gooberman et al. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Kim
Patent Examiner
Art Unit 1617

Jmk
July 5, 2007